

1. (Original) Highly pure cefditoren pivoxil, wherein the cefditoren pivoxil has a purity greater than 98.5% and contains less than 1.0% of E-isomer impurity and less than 1% of  $\Delta^2$ -isomer impurity.
2. (Original) The compound according to claim 1, wherein the compound is in an amorphous form.
3. (Original) The compound according to claim 2, wherein the compound has a XRD pattern as depicted in Figure I.
4. (Original) The compound according to claim 1, wherein the compound is in a crystalline form.
5. (Original) The compound of claim 4, wherein the compound has a XRD pattern as depicted in Figure II.
6. (Original) A process for preparing crystalline cefditoren pivoxil from amorphous cefditoren pivoxil, the process comprising:
  - a) (i) adding amorphous cefditoren pivoxil to an organic solvent optionally containing water and/or (ii) adding an organic solvent optionally containing water to amorphous cefditoren pivoxil;
  - b) crystallizing the product from the reaction mixture; and
  - c) isolating crystalline cefditoren pivoxil.
7. (Original) The process according to claim 6, wherein the organic solvent is one or more of an alcohol, a ketone, an ester, a cyclic ether, a nitrile, a glycol, a chlorinated hydrocarbon, or a mixture thereof.
8. (Canceled)
9. (Canceled)
10. (Canceled)
11. (Canceled)
12. (Canceled)
13. (Canceled)

14. (Original) The process according to claim 7, wherein the organic solvent contains about 0.01 to about 50% by weight of water.
15. (Original) The process according to claim 6, wherein the reaction mixture is stirred at a temperature of about  $-20^{\circ}\text{C}$  to about  $100^{\circ}\text{C}$  to crystallize.
16. (Original) The process according to claim 6, wherein the crystallization temperature is kept in the range of about  $0^{\circ}\text{C}$  to about  $60^{\circ}\text{C}$ .
17. (Original) The process according to claim 6, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil having a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
18. (Original) A process for preparing an amorphous form cefditoren pivoxil from crystalline cefditoren pivoxil, the process comprising:
  - a) dissolving crystalline cefditoren pivoxil in a first organic solvent;
  - b) adding a second organic solvent to the solution or adding the solution to the second organic solvent in optional order of succession to precipitate cefditoren pivoxil; and
  - c) isolating the amorphous cefditoren pivoxil from the reaction mixture.
19. (Original) The process according to claim 18, wherein the first organic solvent is at least one water-immiscible or partially miscible solvent.
20. (Original) The process according to claim 19, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.
21. (Original) The process according to claim 18, wherein the second organic solvent is an alkyl ether, a hydrocarbon or a mixture thereof.
22. (Original) The process according to claim 18, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
23. (Original) The process according to claim 18, wherein the dissolution of crystalline cefditoren pivoxil in the first organic solvent is effected by initially dissolving crystalline cefditoren pivoxil in a third organic solvent.

24. (Original) The process according to claim 23, wherein the third organic solvent is one or more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane, methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.
25. (Original) A process for preparing an amorphous form of cefditoren pivoxil, the process comprising the steps of:
  - a) dissolving crystalline cefditoren pivoxil in a first organic solvent;
  - b) removing the first organic solvent from the reaction mixture; and
  - c) isolating the amorphous form of cefditoren pivoxil.
26. (Original) The process according to claim 25, wherein the first organic solvent is at least one water-immiscible or partially miscible solvent.
27. (Original) The process according to claim 26, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.
28. (Canceled)
29. (Canceled)
30. (Canceled)
31. (Original) The process according to claim 25, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
32. (Original) A process for preparing a highly pure amorphous form of cefditoren pivoxil from crystalline form which comprises the steps of:
  - a) dissolving a crystalline form of cefditoren pivoxil in an organic solvent optionally containing water; and
  - b) freeze drying or lyophilizing the solution to get highly pure amorphous form of cefditoren pivoxil, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
33. (Original) The process according to claim 32, wherein the organic solvent comprises at least one water-immiscible or partially miscible solvent.

34. (Original) The process according to claim 33, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.
35. (Canceled)
36. (Original) A process for preparing a highly pure amorphous form of cefditoren pivoxil from crystalline form, the process comprising the steps of:
- a) dissolving the crystalline cefditoren pivoxil in an acid, optionally in the presence of a water miscible organic solvent;
  - b) adding water to the solution in an amount sufficient to precipitate the cefditoren pivoxil from the solution; and
  - c) isolating the highly pure amorphous cefditoren pivoxil from the solution, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
37. (Canceled)
38. (Previously Amended) The process according to claim 37, wherein the ~~organic~~ acid is one or more of C<sub>1-12</sub> alkyl or aryl carboxylic acids, C<sub>1-10</sub> alkyl or aryl sulphonic acids, hydrochloric acid, nitric acid, sulphuric acid, phosphoric acid or a mixture thereof.
39. (Canceled)
40. (Canceled)
41. (Canceled)
42. (Canceled)
43. (Original) The process according to claim 42, wherein water miscible organic solvent is one or more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane, methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.
44. (Canceled)

45. (Original) A pharmaceutical composition comprising a highly pure amorphous or crystalline form of cefditoren pivoxil and a pharmaceutically acceptable carrier, wherein the cefditoren pivoxil is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
46. (Original) A method of treating infections caused by gram positive, gram negative and resistant strains of bacteria comprising administering to a mammalian host in need thereof a therapeutically effective amount of the highly pure amorphous or crystalline form of cefditoren pivoxil, wherein the cefditoren pivoxil is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.